

**REMARKS**

This amendment is submitted in response to the Office Action mailed December 20, 2002. Based on the above amendments and the following remarks, it is submitted that pending claims 1-10, 13-21 and 24 are now in allowable form, as well as newly added claims 25-28. The amendments made herein are supported by the specification and claims as originally filed. As such, it is submitted that no new matter has been added by way of this amendment.

Claims 1, 9, 10, 14, 20 and 21 stand rejected under 35 U.S.C. 101. Claims 1-4 and 7-13 stand rejected under 35 U.S.C. 102(b) as anticipated by Gandorfer et al. (Br. J. Ophthalmol. 2001; 85:6-10). Claims 1-10, 13-21 and 24 stand rejected under 35 U.S.C. 102(b) as being anticipated by Trese et al. (American Academy of Ophthalmology, ISSN 01610-6420). Lastly, claims 1-10, 13-21 and 24 stand rejected under 35 U.S.C. 102(a) as being anticipated by Shi et al. (Graefe's Arch. Clin. Exp. Ophthalmol. (2002) 240:56-62).

**Remarks Directed to Rejection of  
Claims 1, 9, 10, 14, 20 and 21 under 35 U.S.C. 101**

These claims stand rejected under 35 U.S.C. 101 because Applicant "cannot claim a body part such as the eye, or pathological condition." (Paper No. 4, page 2, section 1).

According to the revised interim utility guidelines training materials, it is stated that "Since most diseases or conditions can be treated, rejections under 35 U.S.C. §101 for treatment claims should rarely be made." Applicant submits that the recitation of an anatomical portion or a pathological condition within the body of a claim does not constitute in itself a claim to that particular anatomical feature or pathological condition but rather merely affords contextual basis for the claim. This is especially true in the present case where the claims are process claims. A process recites a series of steps to be carried out and

is not directed to an anatomical object or condition. While Applicant is amenable to proposed claim language changes to remove the offending reference to anatomical features or pathological conditions, it is respectfully submitted that a rejection of pending claims 1, 9, 10, 14, 20 and 21 under 35 U.S.C. 101 on this basis is misplaced and it is requested that it be withdrawn.

**Remarks Directed to Claims Rejections under 35 U.S.C. 102**

It is a tenet of patent law that an anticipatory reference must disclose all of the claimed elements, arranged as in the claim. It is submitted that the prior art references of record fail to disclose the plasmin quantities of independent claims 1 and 14 necessary to induce vitreous liquefaction.

**Remarks Directed to Rejection of Claims 1-4, 7-10 and 13 under 35 U.S.C. 102(b) as Anticipated by Gandorfer et al.**

Claim 1 recites a process for vitreous liquefaction including “delivering a dose of a plasmin composition of less than 0.4 international units into the vitreous body of an eye.” (Claim 1, lines 2-3).

In contrast to claim 1, Gandorfer et al. neither teaches nor contemplates the introduction of a quantity of plasmin of less than 1 unit into a subject eye. Further, Gandorfer et al. nowhere teaches the liquefaction of the vitreous therein.

In light of the above amendments and remarks, reconsideration of the rejection of claims 1-4, 7-10 and 13 under 35 U.S.C. 102(b) as anticipated by Gandorfer et al. is hereby solicited.

**Remarks Directed to Rejection of Claims 1-10, 13-21 and 24 under 35 U.S.C. 102(b) as Being Anticipated by Trese et al.**

Claim 1 recites a process for vitreous liquefaction including “delivering a dose of a plasmin composition of less than 0.4 international units into the vitreous body of an eye.”

(Claim 1, lines 2-3). Likewise, claim 14 recites “delivering a dose of a plasmin composition of less than 0.4 international units comprising autologous plasmin into a vitreous body of a subject human eye.” (Claim 14, lines 2-3). Trese et al. is cited for teaching the delivery of autologous human plasmin into an eye vitreous body, incubating and delivering a plasmin inhibitor. Applicant submits that Trese et al. fails to teach the limitation of independent claim 14 with respect to plasmin delivery of less than 0.4 international units to induce vitreous liquefaction. Indeed, Trese et al. teaches that a dose of 0.4 international units is insufficient to induce vitreous liquefaction even though this dosage is optimal for producing a vitreal detachment. (See Trese et al., page 1610, column 1, first full paragraph).

In light of the above amendments and remarks, reconsideration of the rejection of claims 1-10, 13-21 and 24 under 35 U.S.C. 102(b) as anticipated by Trese et al. is hereby solicited.

**Remarks Directed to Rejection of Claims 1-10,  
13-21 and 24 as Being Anticipated by Shi et al.**

Claim 1 recites a process for vitreous liquefaction including “delivering a dose of a plasmin composition of less than 0.4 international units into the vitreous body of an eye.” (Claim 1, lines 2-3). Likewise, claim 14 recites “delivering a dose of a plasmin composition of less than 0.4 international units comprising autologous plasmin into a vitreous body of a subject human eye.” (Claim 14, lines 2-3). Shi et al. is cited for teaching the delivery of autologous human plasmin into an eye vitreous body, incubating and delivering a plasmin inhibitor. Applicant submits that Shi et al. fails to teach the limitation of independent claim 14 with respect to plasmin delivery of less than 0.4 international units to induce vitreous liquefaction.

Shi et al. is cited for teaching the delivery of autologous human plasmin into the vitreous body of an eye, incubating the same and delivering a plasmin inhibitor. Shi et al. is also cited as disclosing a plasmin dose of between 0.1 and 1 units of plasmin.

Applicant submits that Shi et al. fails to teach the delivery of plasmin in doses between 0.1 and 1 units of plasmin. Rather, Shi et al. is submitted to only teach the delivery of plasmin in doses of 0, 1, 2 or 3 units concentrated into 0.1 ml injection volumes. (See Shi et al., page 57, column 1, "Injection of plasmin"). It is respectfully submitted that no other dosages of plasmin are taught in Shi et al. Shi et al. therefore fails to teach the limitation of independent claims 1 and 14 with respect to plasmin delivery of less than 0.4 units to induce vitreous liquefaction. Additionally, it is submitted that Shi et al. nowhere teaches liquefaction of the vitreous therein.

Applicant further submits that Shi et al. was published only after reduction of the present invention to practice. Applicant reserves the right to file a declaration under 37 CFR 1.131 to this effect in due course of the prosecution should the Examiner maintain the rejection of pending claims 1-10, 13-21 and 24 as anticipated by Shi et al.

In light of the above amendments and remarks, reconsideration of the rejection of claims 1-10, 13-21 and 24 under 35 U.S.C. 102(a) as anticipated by Shi et al. is hereby solicited.

### **Summary**

Claims 1-10, 13-21 and 24-28 are the claims pending in this application. Independent claims 1 and 14 have been amended, and claims 11, 12, 22 and 23 have been canceled. Claims 25-28 have been newly added. Each pending claim is believed to be in proper form and directed to allowable and patentable subject matter. Reconsideration and allowance of the claims and the passing of this application to issue are solicited. If the Examiner finds to

the contrary, it is respectfully requested that the undersigned in charge of this application be called at the telephone number given below to resolve any remaining issues.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,



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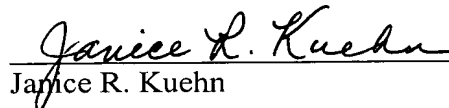
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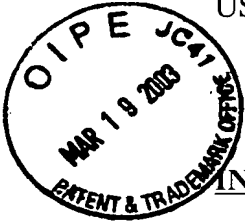
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DATE OF DEPOSIT March 19, 2003

I hereby certify that this paper or fee (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service "Express Mail Post Office To Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to: Commissioner for Patents, Washington, D.C. 20231.



Janice R. Kuehn



VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 1 has been amended as follows:

- 1            1.        (Amended) A process for vitreous liquefaction comprising the steps  
2        of:  
3            delivering a dose of a plasmin composition of less than 0.4 units into a  
4        vitreous body of a subject human eye; and  
5            incubating the plasmin composition in the vitreous body for a predetermined  
6        amount of time to create a liquefied vitreous.

Claims 11 and 12 have been canceled.

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Claim 14 has been amended as follows:

- 1            14.        (Amended) A process for vitreous liquefaction comprising the steps  
2        of:  
3            delivering a dose of a plasmin composition of less than 0.4 units comprising  
4        autologous plasmin into a vitreous body of a subject human eye; and  
5            incubating the plasmin composition in the vitreous body for a predetermined  
6        amount of time to induce vitreous liquefaction.

Claims 22 and 23 have been canceled.

New claims 25-28 have been added.